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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/423,943

03/08/00

SAMPATH

K

00960-570

EXAMINER

HM12/1122

ANDRES, J

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BOSTON MA 02111

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

11/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/423,943	Applicant(s) SAMPATH ET AL.	
	Examiner Janet L Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-122 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-28, drawn to methods of evaluating compounds, classified in class 435, subclass 7.1.

Group II, claim(s) Claims 29-75, drawn to compounds and methods for enhancing non-skeletal tissue formation, classified in class 514, subclass 2.

Group III, claims 76-122, drawn to compounds and methods for inducing bone or cartilage formation, classified in class 514, subclass 2.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the factors are known in the art, as stated by applicant on p. 22-23 of the application. Thus there is no special technical feature linking the inventions. The groups are further drawn to different methods with different steps, different considerations, different outcome measures, and different status in the art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I:

Morphogen:

- a) OP1
- b) OP2
- c) OP3
- d) BMP2
- e) BMP3
- f) BMP4
- g) BMP5
- h) BMP6
- i) BMP9
- j) BMP-10
- k) BMP-11
- l) BMP-12
- m) BMP-15
- n) BMP-3b
- o) DPP
- p) Vg1
- q) Vgr 60A protein
- r) GDF-1
- s) GDF-3

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t) GDF-5

u) GDF-6

v) GDF-7

w) GDF-8

x) GDF-9

y) GDF-10

z) GDF-11

aa) OPX and generic sequences

Tissue type:

a) skeletal

b) lung

c) cardiac

d) liver

e) neural

f) pancreas

g) uterine

h) thyroid

i) renal

j) dental or periodontal

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims are generic: Claims 1-4 and 8-22.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the morphogens are distinct proteins already known in the art. Each of the tissue types are distinct, contain different cell types, and have different regenerative capabilities. Thus there is no single technical feature that links either the different morphogens or the different tissue types.

For Group II:

Morphogen:

- a) OP1
- b) OP2
- c) OP3
- d) BMP2
- e) BMP3
- f) BMP4

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g) BMP5

h) BMP6

i) BMP9

j) BMP-10

k) BMP-11

l) BMP-12

m) BMP-15

n) BMP-3b

o) DPP

p) Vg1

q) Vgr 60A protein

r) GDF-1

s) GDF-3

t) GDF-5

u) GDF-6

v) GDF-7

w) GDF-8

x) GDF-9

y) GDF-10

z) GDF-11

aa) OPX and generic sequences

Tissue type:

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- a) lung
- b) cardiac
- c) liver
- d) neural
- e) pancreas
- f) uterine
- g) thyroid
- h) renal
- i) dental or periodontal

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims are generic: Claims 29-32, 36-50, and 57-69

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special

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technical features for the following reasons: Each of the morphogens are distinct proteins already known in the art. Each of the tissue types are distinct, contain different cell types, and have different regenerative capabilities. Thus there is no single technical feature that links either the different morphogens or the different tissue types.

For Group III:

Morphogen:

- a) OP1
- b) OP2
- c) OP3
- d) BMP2
- e) BMP3
- f) BMP4
- g) BMP5
- h) BMP6
- i) BMP9
- j) BMP-10
- k) BMP-11
- l) BMP-12
- m) BMP-15
- n) BMP-3b
- o) DPP
- p) Vg1

- q) Vgr 60A protein
- r) GDF-1
- s) GDF-3
- t) GDF-5
- u) GDF-6
- v) GDF-7
- w) GDF-8
- x) GDF-9
- y) GDF-10
- z) GDF-11
- aa) OPX and generic sequences

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims are generic: Claims 76-97 and 104-116

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the morphogens are distinct proteins already known in the art. Each of the tissue types are distinct, contain different cell types, and have different regenerative capabilities. Thus there is no single technical feature that links either the different morphogens or the different tissue types.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

November 20, 2000


YVONNE EYLER, PH.D
PRIMARY EXAMINER